SCHOOL OF MEDICINE

COLLEGE OF MEDICINE AND HEALTH SCIENCE

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TREATMENT OUT COMES OF FOOD BY PRESCRIPTION AND ASSOCIATED FACTORS AMONG ADULT HIV/AIDS PATIENTS IN GONDAR UNIVERSITY HOSPITAL, NORTH WEST ETHIOPIA, 2015

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Title: TREATMENT OUT COMES OF FOOD BY PRESCRIPTION AND ASSOCIATED FACTORS AMONG ADULT HIV/AIDS PATIENTS IN GONDAR UNIVERSITY HOSPITAL, NORTH WEST ETHIOPIA, 2015.

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Acronyms

AIDS	Acquired Immuno Deficiency Syndrome
ART	Anti Retro viral Therapy
ARV	Anti Retro Viral
BMI	Body Mass Index
CD4	Cluster Differentiation 4
CI	Confidence Interval
FAO	Food and Agriculture Organization
FBP	Food By Prescription
FMOH	Federal Ministry Of Health
GUH	Gondar University Hospital
HAART	Highly Active Anti Retroviral Therapy
HIV	Human Immune deficiency Virus
HR	Hazard Ratio
MAM	Moderate Acute Malnutrition
NACS	Nutritional Assessment, Counseling, and Support
OR	Odds Ratio
PEPFAR	President's Emergency Plan For AIDS Relief
PLWH	People Living With HIV
RUTF	Ready to Use Therapeutic Food
SAM	Sever Acute Malnutrition
USAID	United States Agency for International Development
WFP	World Food Program
WHO	World Health Organization

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ABSTRACT

Introduction The links between malnutrition and HIV run both ways that malnutrition predicts illness or death among people living with HIV. Integrating nutritional intervention with HIV/AIDS care is crucial and identifying its treatment outcome is important.

Objective This study aimed to assess the treatment outcome and associated factors of food by prescription among adult HIV positive individuals in Gondar University Hospital.

Methods Institution based cross sectional study was conducted from May 20 to June 10, 2015. Participants were 363 adult HIV positive individuals who had nutritional intervention with food by prescription program at Gondar University Hospital. Sampling was done by using systematic random sampling technique. Data was extracted with appropriate data extraction format from the food by prescription registration book and patient cards. Descriptive statistics was used to describe the study population in relation to relevant variables. Analysis was carried out using Logistic regression to see the effects of independent variables on the dependent variable.

Result This study included 363 individuals with the mean age of 34.59 (SD ±8.986 years) and among those participants 87(24%) of them were recovered from malnutrition and 276(76%) were failed to recover including 25.6% of non-responders, 48.8% defaulter, and 1.7% died. Logistic regression indicates that base line nutritional status at entry (AOR= 4.466 95%CI 2.201, 9.064) and presence of opportunistic infections (AOR=0.239 95%CI 0.057, 0.998) were significantly associated with recovery from malnutrition.

Conclusion and Recommendation In this study 24% of participants were recovered from malnutrition. Base line nutritional status at entry was positively associated and presence of opportunistic infection was negatively associated with recovery. Counseling about adherence and adjusting of appointment days are important to improve the outcome of food by prescription among patients on chronic HIV care.

1. INTRODUCTION

1.1. STATEMENT OF THE PROBLEM

The Human Immune deficiency Virus/ Acquired Immune Deficiency Syndrome (HIV/AIDS) is a global pandemic. According to WHO Report of 2013, Globally 35.0 million (33.2 million- 37.2 million) people were with HIV. From the total 24.7 million (23.5 million -26.1 million)people living with HIV are living in Sub-Saharan Africa (1) . In Ethiopia an estimated 793,700 (716,300-893,200) people are living with HIV(1) and currently 7,681 peoples have follow up and chronic care from Gondar University Hospital.

Up to 50% of HIV infected people have malnutrition in many parts of the world (2). Sub-Saharan Africa has the highest proportion of undernourished people in the world, along with the highest number of HIV infected people. Thus as a result of high levels of food insecurity, many HIV patients are under nourished (3).

Malnutrition and weight loss are common clinical findings among HIV infected people (4). Malnutrition in these patients has multiple determinants, including increase in demand, reduction in food intake, and nutrient mal absorption. In settings both with and without wide spread food insecurity, weight loss and wasting are significant predictors of mortality among HIV infected people, even for those who are on HAART. The links between malnutrition and HIV run both ways that weight loss strongly predicts illness or death among HIV infected people. Loss of as little as 3-5% of body weight significantly increases the risk of death. Losing more than 10% is associated with a 4 to 6 fold greater risk (5).

Proper treatment and supplementation of under nutrition is necessary to restore the immune system, to prevent opportunistic infections and to improve response to medical treatment and that results in improving quality of life of HIV infected people (6).

The food by prescription program is one of the strategies that addresses under nutrition among HIV infected people and their vulnerable family members through nutritional assessment, counseling, and support (NACS)(6, 7).

Ethiopia begins these program in the summer of 2010 with technical assistance of Save the Children US.FMOH has launched a comprehensive National Nutritional program, which includes nutrition and HIV/AIDS as part of its complete service delivery(6, 8). Ethiopia has integrated HIV and nutrition intervention based on the patient's nutritional status. Beneficiaries are those who have Moderate Acute Malnutrition (MAM) and Sever Acute Malnutrition (SAM). Treatment is with Ready-to-Use Foods (RUTF) which is given in two forms

- Ready-to-use Therapeutic Foods (RUTF) (plumpynut) for SAM
- Ready-to-use Supplementary Foods(RUSF) (plumpysup) for MAM

Both are nutrient dense foods with a multitude of ingredients which requires no preparation and are usually packaged in individual doses given up to six months. The food is used much like a medical prescription intended to address malnutrition, so that the disease can be treated more effectively (2, 6, 9).

HIV infected adults who present with malnutrition at participating health facilities are prescribed food rations according to their nutritional status. The rations are prescribed during monthly appointments together with client's ART medication, and are distributed directly from clinic pharmacies. Clients are monitored closely by health facility staff who are collecting both anthropometric and disease progression data during monthly appointments (10).

1.2. LITRATURE REVIEW

1.2.1. Relationships of Malnutrition and HIV Infection

Malnutrition and HIV infection have a direct relationship as malnutrition hastens disease progression and death. People living with HIV are vulnerable to having a poor nutritional status because of their poor food intake (loss of appetite, mouth ulcers, and food insecurity), increase in demand (altered metabolism) and mal absorption (6, 7).

One factor behind HIV-related weight loss is increased energy expenditure. People with HIV tend to burn around 10% more calories while resting compared to those who are uninfected. The current WHO recommendation for the nutrient requirements of people living with HIV call for increases in energy over the intake levels recommended for healthy non HIV infected individuals of the same age, sex, and level of physical activity (2).

1.2.2. Effect of Malnutrition on Survival among HIV Positive Individuals

Although increased availability of first line HAART in low and middle income countries has significantly reduced mortality and morbidity amongst HIV infected people, under nutrition and weight loss act as strong predictors of excessive early mortality possibly due to poor immune reconstitution (8). A retrospective cohort study done in Malawi showed that low BMI is a well established risk factor for death in HIV infected persons, whether they are on ART or not (9).

Weight loss and under nutrition are well established predictors of mortality in HIV infected patients (10).A retrospective cohort study conducted among HIV positive patients on ART in eastern Ethiopia showed that, who reported to have lost a weight of more than 10% at base line were five times more likely to die compared to those who did not (11).

A retrospective and descriptive cohort study conducted in Cambodia showed that malnutrition appeared to be a strong and independent risk factor of death. When BMI decreased below 16kg/m^2,there is increased risk of death (12).

1.2.3. Nutritional Interventions and Their outcome

Poor nutritional status may hasten progression to AIDS-related illness, undermine adherence and response to ART and exacerbate socioeconomic impacts of the virus. To prevent such problems high income countries and international organizations like World Food Program (WFP), World Health Organization (WHO), President's Emergency Plan For AIDS Relief (PEPFAR), Food and Agriculture Organization (FAO), and United States Agency for International Development (USAID) recommend nutritional support as a part of the care provided to people living with HIV (13).

Nutritional interventions like ready-to-use food therapy are critical components of a comprehensive care of HIV/AIDS. In many conditions nutritional interventions can help break the infection and malnutrition cycle by helping people restoring their immune function, reducing the incidence of opportunistic infections associated with HIV infection, delays the disease progression of HIV infection, improving quality of life and ultimately reducing morbidity and mortality associated with HIV (2).

Food is required for processing, absorption, and optimal clinical benefits for certain ART regimens. Food insecurity it self can interfere with medication adherence by disrupting daily routines, impairing memory and attention, impeding adherence strategies, and reducing motivation (14).

In places where malnutrition and HIV prevalence is high, better nutritional intervention improves ARV drug adherence and prevents drug resistance and treatment failures(15). A case control study conducted in northern Ethiopia shows that malnutrition and inability to get enough and/or quality food were significantly associated with non-adherence to ART (13). Food insecurity is a primary obstacle to ART drug adherence, so drug adherence is difficult to achieve in an undernourished patient. Studies show that ART

drug adherence was significantly high among participants receiving food supplementation (3).

Nutritional interventions have been successful in the management of HIV and AIDS, and many patients enrolled in to such programs have markedly improve their body weight and adherence to their ARV drugs and follow-ups (6, 13). A retrospective cohort study conducted in Mekelle stated that 62.2% of patients on ready to use food therapy were recovered from malnutrition (2).

In sub-Saharan Africa 15% of the HIV patients in care required nutritional rehabilitation(16). The administration of nutrition therapy in conjunction with an early start of ART might increase the chances of nutritional recovery in severely malnourished HIV patients (16).

Nutritional support with RUTF may be more effective when provided to patients at earlier stages of malnutrition (16). According to the study conducted on impacts and cost effectiveness of FBP on recovery from malnutrition in Ethiopia, closely monitoring the nutritional status of HIV patients and treating malnutrition at early stage is important to achieve optimal recovery from malnutrition (17).

A cross sectional study conducted in Tanzania showed that under weight and wasting among RUTF receivers were 3.0% and 2.8%, respectively, where as in non-RUTF receivers were 12.4% and 16.5%. So the provision of RUTF for at least four months was associated with low proportion of under nutrition status (18) .

A retrospective cohort study done in Malawi stated that subjects who receive RUTF were more likely to increase their BMI than those who do not receive RUTF, but there was no longer a significant effect of supplementary feeding on increase in BMI 12 weeks after the feeding was stopped (9).

A longitudinal study conducted in Kenya and Uganda showed that, 47.4% of patients who have nutritional intervention were recovered from malnutrition, and 13.5% of patients were discharged uncured (non-responder), 22.6% defaulted, 11.9% died, 2.4%

transferred to other facilities, and 2.3% stopped RUTF due to treatment intolerance or other reasons (16).

A study conducted in Ethiopia on impacts of FBP showed that recovery rate was 42%, and non-response rate was 58%. Along with this, factors associated with increased chance of recovery from malnutrition included being female, recent commencement of ART, being moderately rather than severely malnourished, having a CD4 count higher than 200cells/micro liter, and coming from a food insecure house hold. Of whom recovered (according to program protocol), 80% maintained or improved their BMI at ≥ 18.5 at six months after exit. While 20% relapsed to become malnourished (17).

Other retrospective cohort study conducted in Kenya showed that only 13.1% of clients attain a BMI of > 20 and 22.2% attaining BMI > 18.5, and higher nutritional status at base line, younger age, male sex, and not requiring HAART during the study period were associated with a higher rate of attainment of BMI > 20 (10).

In all studies food supplementation improved weight gain and BMI. Food and nutrition security plays in improving drug adherence, prevents acquiring of opportunistic infections and early mortality and improving overall quality of life for HIV patients (3).

1.3. Justification of the Study

Malnutrition is common up to 50% of people living with HIV due to different reasons whether they are on HAART or not. The goal of integrating nutritional intervention with HIV/AIDS care is to reduce HIV associated morbidity and mortality, to improve drug adherence to ARV drugs, to increase survival among HIV infected people and ultimately to improve quality of life of HIV infected people.

The study will provide a base line data for hospital managers, ART clinic staffs, donors who are supporting the FBP program in giving information about treatment responses and factors associated with the treatment outcome of FBP among HIV positive adult individuals based on the evidences generated from the study and that helps in improving quality of life of HIV infected people.

There is no similar studies done in outcomes and associated factors of food by prescription program in Gondar University Hospital. So identifying the actual treatment outcomes and associated factors is mandatory to improve the service delivery process, and to improve outcomes associated with nutritional intervention programs.

2. Objectives

2.1. General objective

The aim of this study was to assess treatment outcomes and associated factors of food by prescription among adult HIV positive individuals in Gondar University Hospital, 2015

2.2. Specific Objectives

- To determine treatment outcome of food by prescription among adult HIV patients in Gondar University Hospital.
- To identify factors associated with treatment outcome of food by prescription among adult HIV patients in Gondar University Hospital.

3. Methods

3.1. Study Design

Institution based cross-sectional study design was conducted.

3.2. Study Area and period

The study was conducted in Gondar University Hospital adult ART clinic from May 20, to June 10, 2015.

Gondar University Hospital is a specialized and teaching hospital found in northwest Ethiopia, which provides service for about five million people in Gondar town and for 23 woredas and for neighboring region, Tigray.

Gondar University Hospital ART clinic starts its payment free HIV/AIDS care and service on 1997E.C.Currently, 7,681 adult HIV/AIDS clients have chronic care and follow up service in this ART clinic (GUH data base).

3.3. Source population

All adult HIV positive individuals who have follow up in GUH were considered as source population.

3.4. Study population

Adult HIV positive individuals who had nutritional intervention with food by prescription program from September 11, 2013 to August 31, 2014 at GUH on ART clinic.

3.4.1. Inclusion criteria

Adult HIV positive individuals age greater than 15 years, who had nutritional intervention and registered in the food by prescription registration book from September 11, 2013 to August 31, 2014.

3.4.2. Exclusion criteria

- Those, who are transferred out to other health facility.

- Incomplete patient records.

3.5. Sample size determination and Sampling procedure

Sample size was determined by using single population proportion formula using 50% recovery rate from malnutrition with 95% confidence interval and a 5% of margin of error.

$$n = \frac{(Z\alpha/2)^2(P)(1-P)}{d^2}$$

Where n = sample size

P= proportion of recovery from malnutrition 50%

Z = standard normal distribution curve value for the 95% confidence interval (1.96)

d= margin of error (5%)

$$n = \frac{(1.96)^2 (0.5) (1-0.5)}{(0.05)^2}$$

$$= 384$$

The population size is less than 10,000, using correction formula

$$Nf = n/1+n/N$$

$$Nf = 384/1+384/7681$$

Nf = 366 +10% possible data incompleteness

Nf = 366+37 = 403

3.6. Sampling procedure

Selection of each record of patients was done by systematic random sampling method using the food by prescription registers as sampling frame until the determined sample size was obtained.

There were 812 total HIV infected patients who were enrolled in to FBP program from September 11, 2013 to August 31, 2014.

N= 812 n= 403

N/n= 812/403 =K = 2.01

So sample was taken every second interval until the determined sample size was obtained.

3.7. Variables of the Study

3.7.1 . Dependent Variable

- Treatment outcome (Good or poor)

3.7.2 .Independent Variables

Socio demographic factors

- Sex
- Age
- Educational status
- Occupation
- Residence
- Religion

- Marital status

Clinical Factors

Base line Nutritional status

- Sever Acute malnutrition
- Moderate Acute malnutrition

ARV Treatment Status

- On HAART
- On pre ART

CD4 count at Admission

- <200 cells/m^3
- 200 – 350 cells/m^3
- > 350 cells/m^3

Presence of Opportunistic Infections

- Tuberculosis, TB & other OI
- Diarrhea, mouth ulcer/ oral thrush, pneumonia, meningitis, CNS toxoplasmosis

WHO clinical stage

- stage 1
- stage 2
- stage 3
- stage 4

3.8. Operational Definitions

Good outcome (Graduated/ Recovered):- Patients reached a BMI of 18.5kg/m² for two consecutive visits within 3 months for MAM and within 6 months for SAM.

Poor outcomes

Non-response/ Unrecovered:- Participants who did not reach a BMI of 18.5kg/m² for two consecutive visits within 3 months for MAM and within 6 months for SAM.

Defaulter : Participants did not reach a BMI of 18.5kg/m² and dropped out of the program before the end of treatment.

Died : Participant died during the course of treatment and his/her death is documented in the registration book.

3.9. Data collection

All available information on food by prescription registration book and patient cards was checked and an appropriate data extraction format was prepared.
Data was extracted from the food by prescription registration book and patient cards from September 11, 2013 to August 31, 2014 by the help of two supervisors and four Nurses/Health officers who have experience in HIV/AIDS care.

During the data collection process the filled data extraction formats were checked for their completeness, consistency and accuracy by the principal investigator every day.

3.10 Data processing and Analysis

The data gathered through the data extraction formats was entered in to Epi info 7 and transferred to SPSS version 20.

Data cleaning was performed to check for accuracy, and consistency. Any consistency error identified during data entry was corrected after revision of the data extraction format. The cleaned and edited data was ready for statistical analysis.

To explain the study population in relation to relevant variables descriptive statistics (frequency, mean, SD, percentage) was used. Bivariate and multivariate logistic regression was used to assess the association between outcome and explanatory variables. Association between dependent and independent variables was assessed by bivariate logistic regression analysis and its strength was presented using odds ratios and 95% confidence interval and P-value of <0.2 and finally the variables which have significant association was identified on the basis of OR, with 95% confidence interval and P-value of <0.05. The result of the analysis was presented using tables, graphs and texts.

4. Ethical Consideration

Ethical clearance was obtained from School of Medicine Ethical review board, University of Gondar, and permission for conducting the study was obtained from the Chief Clinical Director of the hospital. The department head of the ART clinic gave the consent for extracting data from FBP registration books and patient cards. Patient names and identification numbers was not extracted so as to ensure confidentiality of patient's information.

5. Dissemination of Results

The result of the study will be disseminated and communicated to University of Gondar and will presented in annual research conference of University of Gondar if it is selected, Amhara regional health bureau, FMOH and other interested governmental and non- governmental organizations. Publication in scientific journal and online dissemination will be considered.

6. RESULTS

6.1. Socio-Demographic Characteristics

The study included a total of 363 eligible patient records on food by prescription program. Among those 223 (61.4%) of them were females and the mean age (±SD) of respondents was 34.59 (±8.98) years. Regarding the educational status, 126 (34.7%) were illiterate and the rest 237 (65.3%) had attended at least formal education. As to marital status, 133 (36.7%) were married and 120 (33.1%) of them were in union. Out of the total respondents, 332 (91.5%) were orthodox Christian followers. Most 272 (74.9%) of study subjects were unemployed. Out of the total study subjects, 293 (80.7%) of them were urban dwellers (Table 1).

Table 1 : Socio-Demographic Characteristics of study participants at GUH Adult ART clinic, From September 11, 2013 to August 31,2014, (n=363)

Characteristics		Number	Percent
Sex	Male	140	38.6
	Female	223	61.4
Age	15-24	29	8.0
	25-34	166	45.7
	35-44	114	31.4
	45-54	41	11.3
	≥55	13	3.6
Residence	Rural	70	19.3
	Urban	293	80.7
Marital status	Single	89	24.5
	Married(union)	120	33.1
	Married(separated)	13	3.6
	Divorced	96	26.4
	Widowed	45	12.4
Religion	Orthodox	332	91.5
	Muslim	28	7.7
	Protestant	3	0.8
Educational status	No education	126	34.7
	Primary	108	29.8
	Secondary	94	25.9
	Tertiary	35	9.6
Employment	Employed	91	25.1
	Unemployed	272	74.9

6.2. Participants Nutritional and HIV/AIDS Related Characteristics during Enrollment

At base line, 136 (37.5%) were on Sever Acute Malnutrition (BMI of <16kg/m²), 227 (62.5%) were on Moderate Acute Malnutrition (BMI of 16-17.99kg/m²). Most of participants at enrollment of FBP program, 288 (79.3%) were on HAART and the rest 75 (20.7%) were on pre-ART service. Additionally, most patients admitted to FBP program 211 (58.1%) and 90 (24.8%) were on WHO clinical stage 1 and 3 respectively. As to CD4 count at admission 36 (9.9%) had CD4 count of <200 cells/m³, 97 (26.7%) had 200-350 cells/m³ and 230 (63.4%) had a CD4 count of >350 cells/m³. Regarding to opportunistic infections, most participants 268 (73.8%) had no opportunistic infections during enrollment. The rest 95 (26.2%) had opportunistic infections like TB, diarrhea, mouth ulcer/oral thrush, pneumonia, meningitis and CNS toxoplasmosis (Table 2).

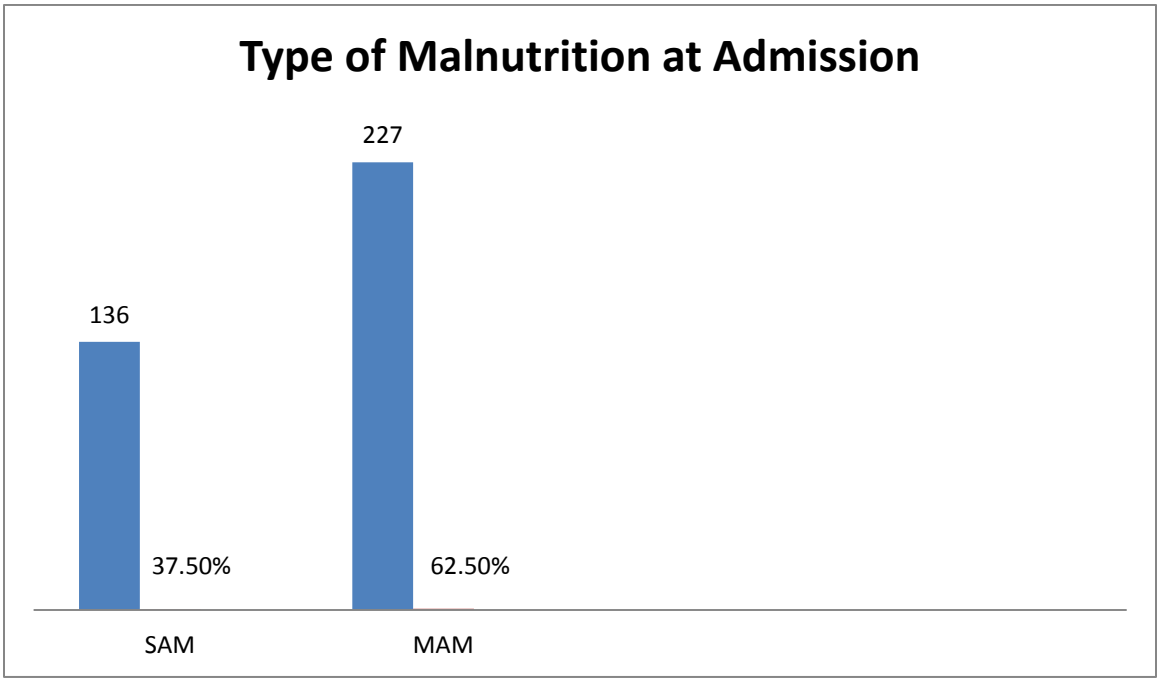

Figure 1 : Type of malnutrition at admission in GUH from September 11, 2013 to August 31, 2014, North West Ethiopia, June 2015.

Table 2 : Participants Nutritional and HIV/AIDS related Characteristics during Enrollment at GUH Adult ART clinic from September 11,2013 to August 31, 2014 (n=363)

Nutritional and HIV/AIDS related Characteristics		Number	Percent
Base line Nutritional status	SAM	136	37.5
	MAM	227	62.5
WHO clinical stage	Stage 1	211	58.1
	Stage 2	27	7.4
	Stage 3	90	24.8
	Stage 4	35	9.6
CD4 count at admission	<200cells/m³	36	9.9
	200-350cells/m³	97	26.7
	>350cells/m³	230	63.4
ART treatment status	On ART	288	79.3
	Pre ART	75	20.7
Presence of Opportunistic infections	TB,TB &Others	50	13.8
	Diarrhea, Mouth ulcer/Oral thrush, other	45	12.4
	No OIs	268	73.8

*****other=Pneumonia,Meningitis,CNStoxoplasmosis

6.3. Treatment Outcome of Food by Prescription among adult HIV/AIDS Patients

From a total of 363 patients enrolled in to Food by Prescription program 87 (24%) were recovered (graduated) from malnutrition. Ninety three (25.6%) of patients were non-responders (didn't recover) according to the FBP exit criteria, 177 (48.8%) were defaulted from the FBP program and 6 (1.7%) were died during the intervention period. The overall failure rate including non-responders, defaulter and death were 276 (76%).

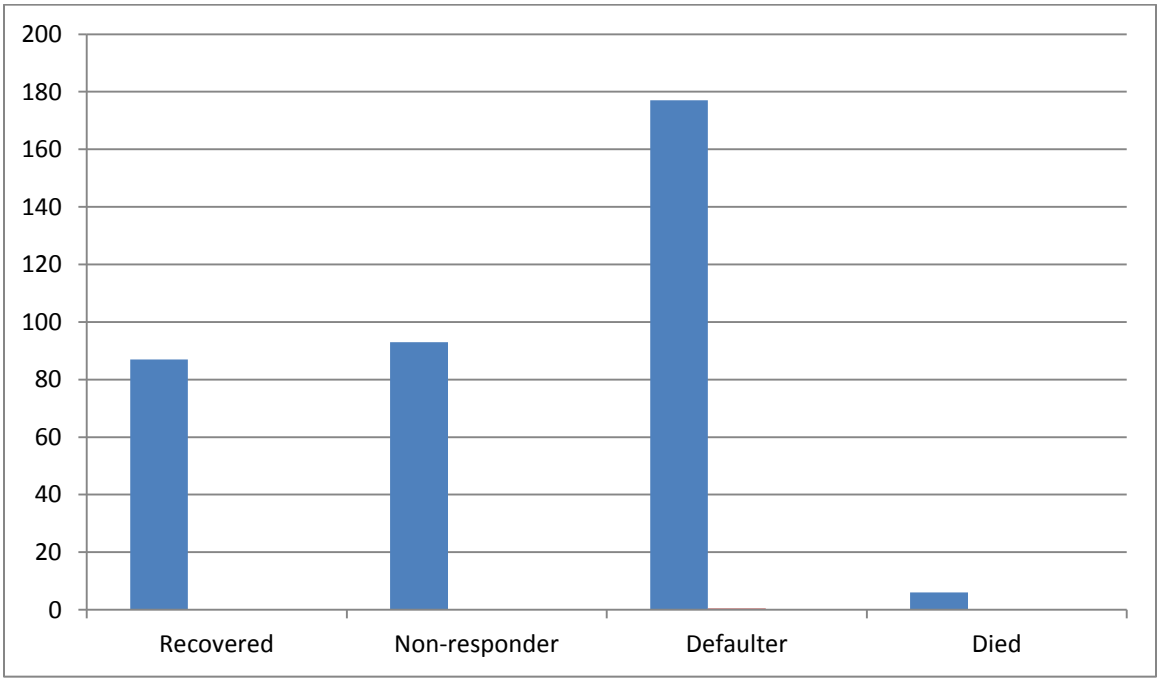

Figure 2 : Treatment outcome of food by prescription among adult HIV positive individuals in GUH from September 11, 2013 to August 31, 2014 , North west Ethiopia.

6.4. Treatment Outcome of FBP in Related to Socio-Demographic, Nutritional and HIV/AIDS Factors

From a total of 363 study subjects, 35 (25%) male participants and 52 (23.3%) female participants were recovered from malnutrition. Regarding to age, from 15-24 years 13 (44.8%), from 25-34 years 41 (24.7%), from 35-44 years 23 (20.2%), from 45-54 years 9 (22%), from ≥ 55 years 1 (7.7%) were recovered from malnutrition. From participants who have no education, 27 (21.4%) were recovered from malnutrition. Those who have primary education 35 (32.4%), secondary education 16 (17%), and tertiary education 9 (25.7%) were recovered from malnutrition according to the exit criteria.

From a total of 227 moderately malnourished patients, 71 (31.3%) were recovered and from 136 severely malnourished patients, 16 (11.8%) were recovered (Table 3).

Table 3: Treatment Outcome of FBP in Related to Socio-Demographic, Nutritional and HIV/AIDS Factors from September 11, 2013 to August 31, 2014 (n= 363)

Variables		Treatment Outcome	
		Recovered	**Unrecovered**
		N (%)	**N (%)**
Sex	Male	35 (25%)	105 (75%)
	Female	52 (23.3%)	171 (76.7%)
Age	15-24	13 (44.8%)	16 (55.2%)
	25-34	41 (24.7%)	125 (75.3%)
	35-44	23 (20.2%)	91 (79.8%)
	45-54	9 (22%)	32 (78%)
	≥55	1 (7.7%)	12 (92.3%)
Educational Status	No education	27 (21.4%)	99 (78.6%)
	Primary	35 (32.4%)	73 (67.6%)
	Secondary	16 (17.0%)	78 (83.0%)
	Tertiary	9 (25.7%)	26 (74.3%)
Marital status	Single	22 (24.7%)	67 (75.3%)
	Married (union)	25 (20.8%)	95 (79.2%)
	Married (separated)	2 (15.4%)	11 (84.6%)
	Divorced	27 (28.1%)	69 (71.9%)
	Widowed	11 (24.4%)	34 (75.6%)
Occupation	Employed	19 (20.9%)	72 (79.1%)
	Unemployed	68 (25%)	204 (75%)
Residence	Rural	17 (24.3%)	53 (75.7%)
	Urban	70 (23.9%)	223 (76.1%)
Religion	Orthodox	80 (24.1%)	252 (75.9%)
	Muslim	6 (21.4%)	22 (78.6%)
	Protestant	1 (33.3%)	2 (66.7%)
Base line nutritional	SAM	16 (11.8%)	120 (88.2%)

status	MAM	71 (31.3%)	156 (68.7%)
WHO Clinical Stage	Stage 1	51 (24.2%)	160 (75.8%)
	Stage 2	5 (18.5%)	22 (81.5%)
	Stage 3	22 (24.4%)	68 (75.6%)
	Stage 4	9 (25.7%)	26 (74.3%)
CD4 Count	<200 cells/m^3	12 (33.3%)	24 (66.7%)
	200-350 cells/m^3	18 (18.6%)	79 (81.4%)
	>350 cells/m^3	57 (24.8%)	173 (75.2%)
ARV treatment status	On HAART	65 (22.6%)	223 (77.4%)
	On Pre ART	22 (29.3%)	53 (70.7%)
Presence of OIs	TB, TB & other	15 (30.0%)	35 (70.0%)
	Diarrhea,mouth ulcer/OT,pneumonia, meningitis,CNS toxo	6 (13.3%)	39 (86.7%)
	No OIs	66 (24.6%)	202 (75.4%)

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6.5. Factor Associated with Treatment Outcomes of Food by Prescription

In the bivariate logistic regression analysis conducted to assess possible relationships between treatment outcome of FBP and different variables, age, baseline nutritional status, and presence of opportunistic infections, had association at a p-value of <0.2.

In multivariate analysis, baseline nutritional status, and presence of OIs (diarrhea, mouth ulcer/oral thrush, pneumonia, meningitis, and CNS toxoplasmosis) at enrollment were significantly associated with treatment outcome of FBP at p-value of <0.05.

The odds of participants who are moderately malnourished at base line was 4 times (AOR= 4.466 95%CI 2.201, 9.064) higher for recovery as compared with those who are severely malnourished at entry.

Participants who had opportunistic infections like diarrhea, mouth ulcer/oral thrush, pneumonia, meningitis, and CNS toxoplasmosis were less likely to recover from malnutrition (AOR= 0.239 95%CI 0.057, 0.998) as compared to those who had no opportunistic infections at entry.

Age had association on bivariate logistic regression analysis, but in multivariate logistic regression it was not significant at a p-value of <0.05(Table 4).

Table 4: Logistic Regression of Treatment Outcome of FBP with Predictor Variables among adult HIV positive Individuals in GUH from September11, 2013 to August 31, 2014, (n=363)

Variable		Treatment Outcome		COR(95%CI)	AOR(95%CI)
		Recovered N (%)	Unrecovered N (%)		
Age	15-24	13(44.8)	16(55.2)	1	1
	25-34	41(24.7)	125(75.3)	**0.404(0.179,0.910)**	0.434(0.174, 1.079)
	35-44	23(20.2)	91(79.8)	**0.311(0.131,0.737)**	0.376(0.138, 1.027)
	45-54	9(22)	32(78)	**0.346(0.122,0.980)**	0.389(0.119, 1.272)
	≥55	1(7.7)	12(92.3)	**0.103(0.012,0.896)**	0.103(0.010, 1.080)
Baseline nutritional status	SAM	16(11.8)	120(88.2)	1	1
	MAM	71(31.3)	156(68.7)	**3.413(1.888,6.172)**	**4.466(2.201, 9.064)**
Presence of OIs	No OI	66(24.6)	202(75.4)	1	1
	TB, TB & other OIs	15(30.0)	35(70.0)	1.312(0.674,2.552)	0.853(0.269, 2.706)
	Diarrhea, mouth ulcer/OT, other OIs	6(13.3)	39(86.7)	**0.471(0.191,1.162)**	**0.239(0.057, 0.998)**

*others = Pneumonia, Meningitis, CNS toxoplasmosis

Hosmer and Lemeshow goodness fit test = 0.432

7. Discussion

This study reported that 24% of participants enrolled in to food by prescription program were recovered. This is lower when it is compared with a quasi experimental study conducted in Ethiopia among HIV infected individuals who were on FBP reported that 42% of patients who were enrolled in food by prescription program were recovered from malnutrition(17). Additionally, when it is compared with a study conducted in Mekele that was 62.6% recovery , it is much lower(2). This study shows 76% of failure that includes non-responders, defaulters and died patients. Whereas the study conducted in Mekele shows 37.4% failure and another study conducted in Ethiopia shows 58%. So, this is high failure rate as compared to other studies.

However, the non-responder was almost the same 25.6% in this study and 29.6% in the previous study. Additionally, the death rate was also the same that is 1.7% in this study and 1.9% in the previous study. But the defaulter rate has a big difference that is 48.8% in this study and 5.9% in the previous study. Perhaps this high rate of defaulter may affect the recovery rate of this study(2).

There is a great difference in recovery rate 62.6% in a study conducted in Mekele and 24% in this study. This might be due to including of 320(61.1%) mildly malnourished and 127(24.2%) moderately malnourished study subjects (who have strong association with recovery) by the study conducted in Mekele. But this study included only 136(37.5%) severely malnourished and 227(62.5%) moderately malnourished participants(2).

Other retrospective cohort study conducted in Kenya showed that recovery rate were 35.3% and it is higher as compared to this study(10).

Other longitudinal study conducted in Kenya and Uganda shows 47.4% recovery rate and 13.5% non-responder, 22.6% defaulter and 11.9% death rate comparing to this study recovery rate were 24%, non-responder were 25.6%, defaulter rate were 48.8% and death rate were 1.7%. So results in this study are low in recovery rate and higher in failure rates except the death rate(16).

Factors associated with recovery among adult HIV/AIDS patients who are enrolled in food by prescription program were baseline nutritional status at enrollment and presence of opportunistic infections.

This study presents that moderately malnourished participants have 4 times higher recovery rate than severely malnourished participants. In line with this, study done in Ethiopia on impacts of food by prescription showed that, being moderately malnourished has increased chance of recovery from malnutrition than severely malnourished individuals.

Additionally study done in Mekele on outcome of ready to use therapeutic food showed that, being moderately malnourished at enrollment has 2.5 times higher chance of recovery from malnutrition(2).

Similar to this study, a retrospective study conducted in Kenya showed that base line higher nutritional status were associated with a higher rate of attainment of body mass index(10).

The possible explanation could be mostly severely malnourished patients have opportunistic infections and they are in advanced stages of HIV/AIDS. Additionally, being severely malnourished takes more time for recovery than moderately malnourished ones.

This study shows participants who had opportunistic infections at entry were less likely to recover from malnutrition as compared to those who had no opportunistic infection. Similarly a study conducted in Mekele showed that patients who had opportunistic infections had less chance of recovery from malnutrition. But the most common opportunistic infection in that study was tuberculosis, where as significant opportunistic infection in this study was diarrhea and other opportunistic infections(2).

The possible explanation could be, those who had opportunistic infections during the nutritional intervention period had poor intake of therapeutic food due to poor appetite, mouth ulcers, loss of consciousness and, mal absorption, and increase in demand.

A study conducted in Ethiopia, Mekele, and Kenya showed that CD4 count at entry as well as ART treatment status and WHO clinical stage had association with recovery from malnutrition .But in this study they have no association(2, 10, 17).

A study conducted in Ethiopia on impacts of food by prescription showed that being female was associated with increased chance of recovery, but in other retrospective study conducted in Kenya reported that being male were associated with increased chance of recovery. In contrary to these, this study shows no association between sex and recovery (10, 17).

Retrospective cohort study conducted in Kenya showed that younger age was associated with recovery from malnutrition, where as this study shows no association between age and recovery.

In different studies level of education and employment status were associated with recovery, but this study shows no association.

8. Strengths and Limitations of the Study

8.1. Strengths

Even if the study collected the data from food by prescription registration books and patient cards, it was strictly depends on the outcome BMI not on the outcome category.

8.2. Limitations

The study used secondary data that may limit the ability to gather data about adherence and factors that may influence failure to respond to food by prescription.

It may be difficult to generalize results to patients in other institutions and localities because of differences in diverse professions, educational status and life styles as well as the differences in settings as far as this study was done in referral hospital.

9. Conclusion

Twenty four percent of patients admitted to food by prescription program were recovered from malnutrition and 76% of patients were failed to respond to the therapeutic food (25.6% non responders, 48.8% defaulters and 1.7% died)

Significant factors that affect the recovery rate from malnutrition were base line nutritional status at entry and presence of opportunistic infections during the intervention period.

10. Recommendations

For GUH adult ART Clinic

Strengthening of counseling about nutritional adherence, about the use of therapeutic foods as well as counseling about the duration of management is crucial to improve the outcome of food by prescription and to decrease the defaulter rate among patients on chronic HIV care.

Additionally it is better to adjust the monthly appointments of food by prescription and ARV drugs to make convenient to clients.

For Researchers

This research did not include factors that influence adherence to FBP and it is important to assess in the future studies.

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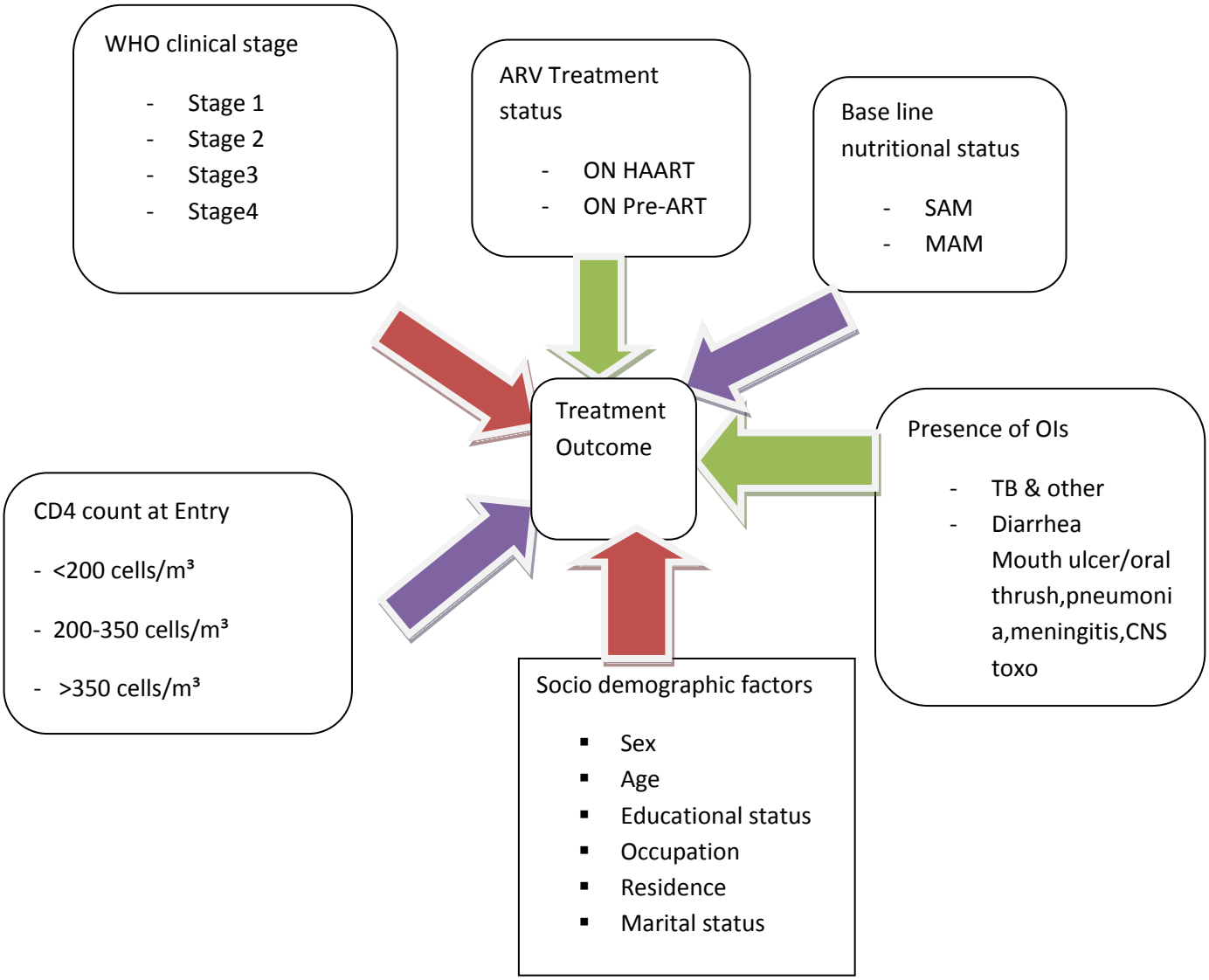
12. Annexes



Conceptual framework adopted from literature review

Data Extracting Tool

Code number
Socio demographic factors
Sex 1. Male
2. female
Age
Educational status
1. No education
2. primary
3. secondary
4. tertiary
Occupation
1. self employee
2. Governmental/NGO employee
3. Other
Marital status
1. single
2. Married (union)
3. Married (separated)
4. Divorced
5. Widowed/ widower
Residence
1. Rural
2. Urban
Religion
1. Orthodox
2. Muslim
3. Protestant
4. Catholic
Base line nutritional status
1. SAM
2. MAM
WHO clinical stage
1. Stage 1
2. Stage 2
3. Stage 3
4. Stage 4

ARV treatment status
1. On HAART
2. Pre-ART
CD4 count at entry
1.<200 cells/m^3
2. 200-350 cells/m^3
3. >350 cells/m^3
Presence of other OIs
1. tuberculosis
2. diarrhea
3.mouth ulcer/oral thrush
4.other
5.TB and other
6.No OIs
Treatment Outcome
1.Graguated
2.non responder
3.Defaulter
4. Died

Name of data collector_____

Signature _____

Date _____

Declaration

I, the under signed, MSC student declare that this thesis is my original work in partial fulfillment of the requirement for the masters degree in clinical tropical infectious disease and HIV medicine.

Meaza Tesfaye

Signature _____

Place of submission: Department of internal medicine, college of Medicine and Health Science, University of Gondar.

Date of submission June 2015

This thesis work has been submitted for examination with our approval as University Advisors.

Advisors

Name	Signature
1. Professor Melkie Edris	_____
2. Mr. Haimanot G/Hiwot (Ass. Professor)	_____

Assurance of the Investigator

The under signed agree to accept responsibility for the scientific, ethical and technical conduct of the research project and for provision of required process report as pre terms and conditions of research and publication office of the University of Gondar.

Name of the student – Meaza Tesfaye

Date June Signature_____

Approval of the advisors

Advisors Name	Signature	Date
1. Prof. Melkie Edris	_____	_____
2. Mr. Haimanot G/hiwot(Ass.Prof.)	_____	_____